

K964860

MAR -3 1997

Section 510(k) Premarket Notification
Summary of Safety and Effectiveness Information

Mark 20 and Mark 25
Irrigating Handengine Controller

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Trade Name: Mark 20 and Mark 25 Hand Engine Controller

Common Name: Dental handpiece controller

Classification Name: Dental handpiece and accessories

2. Establishment Name & Registration Number:

Name: BELL INTERNATIONAL

Number: 2921268

3. Classification:

§ 872.4200 Dental handpiece and accessories. (a) Identification. A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. (b) Classification. Class I. [55 FR 48439, Nov. 20, 1990].

Product Code(s): 76EBW

Device Class: Class I

Classification Panel: Dental

4. Equivalent / Predicate Device(s):

1. The 25-D hand engine and C-310 Console (Controller)

5. Description of the Device:

The new device submission covers two handengine controllers designed to operate the 45E and RX-100 dental handengines. The 45E and the RX-100 are low-voltage DC-motors with E-connector type front ends. Both the 45E and the RX-100 may be operated by the Mark 20 or Mark 25 Controller. Both engines have Off/On or variable speed footswitches. Both engines accept various angled and straight front handpieces on the motor to do different types of dental work or surgical procedures.

The 45E and the RX-100 produce more torque than the original 25D handengine. The 25D offered 320 gram centimeters and the 45EH and RX-100 offer 400 gram centimeters torque.

The Mark 20 and Mark 25 Controllers are typical rheostat based hand engine controllers. The Mark 20 or Mark 25 Controller allows the practitioner infinite control over the speed of the engine and dental front handpiece up to the rated speed capacity of the selected engine and

handpiece. Both the **Mark 20 and Mark 25 Controller** allow the selected hand engine and dental front hand piece to be operated in forward or reverse directions as well as by local control or remote foot switch. Dental or endodontic surgical procedures needing irrigation are supported by the integral fluid pump. The pump is constant speed in the Mark 20 and is variable speed in the Mark 25 unit.

6. Comparison to Predicate Device(s):

The new controllers and handengines are substantially equivalent to the parent model 25-D hand engine with C-310 Console. The model 25D is a pre-amendment device, having been in commercial distribution since 1972. The model 25D along with it's minor modification model, the Mark VI-0 controller has operating speeds of approximately 400 rpm to 20,000 rpm.

The 25D handengine produces torque values of 320 grams centimeters, it is powered by direct current from 3 to 20 volts and it accommodates a ISO chuck of 2.35mm.

The 45EH handengine has a operating range from 1500 to 30,000 rpm and produces torque values of 400 grams centimeters, it operates from 3 to 30 volts direct current and takes a ISO chuck of 2.35mm.

The RX-100 handengine has a operating range from 1500 to 30,000 rpm and produces torque values of 400 grams centimeters, it operates from 3 to 30 volts direct current and takes a ISO chuck of 2.35mm.

The **Mark 20 and Mark 25 Controllers** are substantially equivalent to the **C-310 Console Controller** supplied with the predicate device sold by Bell International as the 25-D hand engine with C-310 Console. The important difference between the **C-310 Console Controller** and the **Mark 20 and Mark 25 Controllers** is the modest difference in control features and the availability of surgical irrigation.

7. Modified Device Data:

Not applicable to this device. This submission covers a new device not a modified device.

8. Applicant / Sponsor Name / Address:

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9. Contact Person:

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10. Manufacturing Facility:

At the present time, the **Mark 20 and Mark 25 Controller** are manufactured in-house by BELL INTERNATIONAL, INC.

11. Comparison Table:

FEATURE	Mark 20 Controller	Mark 25 Controller	25-D hand engine w/ C-310 Console	SE?
Intended Use	Engine, power supply and controller for dental handpiece	Engine, power supply and controller for dental handpiece	Engine, power supply and controller for dental handpiece	Yes
Forward & reverse switch	Yes	Yes	Yes	Yes
Engine torque	400 gram centimeters	400 gram centimeters	320 gram centimeters	no
Automatic Torque Limiting	No	Yes	No	No
Direct - remote selector switch	Yes	Yes	Yes	Yes
Speed Control	Yes	Yes	Yes	Yes
Power Supply	AC - 110-115 VAC, 50/60 Hz	AC - 110-115 VAC, 50/60 Hz	AC - 110-115 VAC, 50/60 Hz	Yes
UL/ETL Compliant	Yes - UL-544	Yes - UL-544	Yes - UL-544	Yes
Engine Models	45E hand engine - RX-100	45E hand engine - RX-100	25D hand engine	Yes
Irrigation Support	Yes - Constant speed	Yes - Variable speed	None	No
Digital speed readout	Yes	Yes	No	No
Voltage output	3 - 30 volts DC	3 - 30 volts DC	2 - 20 volts DC	Yes

12. Safety Standards:

The **Mark 20** and **Mark 25 Controller** are designed to meets UL-544 (medical device) requirements for electrical safety.

13. Sterilization Information:

The device may not be sterilized. Surface disinfecting of the console, cords, foot switch and hand engine and tubing may be accomplished using a number of available non-solvent based commercial germicidal or surface disinfectant preparations. Only the front handpiece of the dental drill may be sterilized.